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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,755	02/28/2002	Yoshimitsu Iida	IIDA=20	3713
1444	7590	03/17/2004	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C.			WEBMAN, EDWARD J	
624 NINTH STREET, NW			ART UNIT	
SUITE 300			PAPER NUMBER	
WASHINGTON, DC 20001-5303			1617	

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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2/26/04

DATE MAILED:

This is a communication from the examiner in charge of your application.
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OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on 10/31/03

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 3-17 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 3-17 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit: 1617

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-6, 10-15⁻¹⁶ are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 3264532 (JP'532) in view of US 4693892 (US '892) JP 4046122 (JP '122) and JP 63215641 (JP '641).

JP '532 teaches soft capsules containing an active vitamin D.

US '892 teaches capsules which have an outstanding light protection effect (column 2 lines 23-24). Soft capsules comprising titanium dioxide and red or yellow iron oxide are disclosed (examples 6, 7).

It would have been obvious to one of ordinary skill to use the soft capsule of US '892 as the soft capsule for JP '532 for the beneficial effect of its property of protection from light. As to the claimed triglyceride, JP '122 teaches such as a carrier for vitamin D in soft capsules. As to the claimed caramel, JP '641 teaches such for light shielding in soft capsules. It would have been obvious to one of ordinary skill to add caramel to the soft capsule of JP '532 for its beneficial effect as additional light shielding in view of JP '641 and to use a fatty acid glyceride in JP '532 for its beneficial effect as a carrier for vitamin D in view of JP'122.

The examiner notes that JP 4046122 (JP '122) should have been cited for the triglyceride limitation rather than JP 63-166824 (JP '824) in the previous non-final rejection filed 8/1/03.

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Applicants argue that JP '532 does not teach vitamin D3 stability. However, it is well-known in the art that vitamin D ^{is} unstable in light (see JP '641 abstract). JP '532 is cited for delivery of vitamin D in soft capsules. Applicants argue that US '892 teach b carotene instability in the presence of titanium. However, the addition of metal oxides eliminates the problem because titanium oxide can be added (column 2 lines 27-29).

Applicants argue that US '892 teach Dihydropyridines rather than vitamin D. However, it is clear from column 2 lines 19-26 that the invention has a general light protection effect and that Dihydropyridines are merely exemplary as being very light sensitive (column 2 lines 35-39). Applicants disclaim but do not exclude the presence of b-carotene. Applicants argue that JP '122 does not teach combining Caramel with Titanium. However, JP '122 is merely cited for the additional light shielding effect that caramel provides.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-¹⁷₇ are rejected under 35 U.S.C. 103(a) as being unpatentable over '532 in view of JP 55141242 (JP '242), US '892 and JP '641.

JP '532 is described in the first 103.

JP '242 teaches titanium dioxide and caramel in capsules for safe coloring (abstract).

It would have been obvious to one of ordinary skill to use titanium dioxide and

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caramel in the soft capsule of JP '532 for the beneficial effect of providing safe coloring in view of JP '242. As to the claimed soft capsule, US '892 and JP '641, both described in the first 103, teach the use of titanium dioxide and caramel respectively in soft capsules.

Applicants argue that JP '532 does not teach light-fast components. However, the combination with the secondary reference provides that improvement. Applicants disclaim but do not exclude the phosphate in JP '242, similarly applicants disclaim but do not exclude the b-carotene of US '892 and the amino acid of JP '641.

Applicants argue a remarkable increase in light stability using the combined claimed ingredients. However, it is not clear as to whether the effect is merely additive, in which case the 103 rejections stand.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-6, 10-15¹⁷ are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '532 in view of JP 4046122 (JP '122), JP '641 and US '892.

JP '532 is discussed in the first 103.

JP '122 teach activated vitamin D in Fatty acid triglyceride in a capsule containing red iron oxide and an opacifier such as titanium white to maintain stability of the vitamin (abstract).

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It would have been obvious to one of ordinary skill to use the soft capsule composition of JP '122 as the vehicle for JP '532 to achieve the beneficial effect of stability of the vitamin.

As to the use of red iron oxide and titanium dioxide in soft capsules, US '892, described in the first 103, teaches such.

As to the claimed caramel, JP '641 described in the first 103, teaches such for light shielding in soft capsules.

It would have been obvious to one of ordinary skill to add caramel to the soft capsule of JP '532 for its beneficial effect of providing additional light shielding in view of JP '641.

Applicants did not traverse this rejection in there response dated 10/31/03.

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

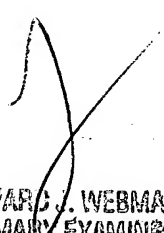
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Edward J. Webman at telephone number 571-272-0633.

Webman/tgd

February 24, 2004



EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500